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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,597	04/09/2001	Zheng Xin Dong	00537-169002	1308

7590 05/14/2004

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EXAMINER

WEGERT, SANDRA L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,597

Applicant(s)

DONG ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 8, 16-22 and 30-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 9-15 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/30/01, 6/27/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Detailed Action

Status of Application, Amendments, and/or Claims

The Information Disclosure Statements, sent 30 April 2001 and 27 June 2002, have been entered into the record. Applicant's election of Invention I (Claims 1-3, 7, 9-15 and 23-29) with SEQ ID NO: 16, in the Paper of 26 January 2004, is acknowledged. The election was made without traverse. Claims 4-6, 8, 16-22 and 30-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Claims 1-3, 7, 9-15 and 23-29 are under examination in the Instant Application.

Informalities

Specification

The disclosure is objected to because of the following informalities:

Continuity

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76). In addition, the listings of the Applicant's applications (for example, page 4 of Specification) should be updated as to their change in status.

Appropriate correction is required.

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Brief description

The instant Specification is lacking a Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74 is required.

Sequence Rules

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, because the CRF submitted 9 April 2003 contains errors. Mandatory line labels or "Features" are missing for almost every SEQ ID NO. Applicant is required to list feature <220> and <223> for each sequence, including information on each residue substitution. Applicants must submit a new CRF, a new paper sequence listing and a new letter stating that the computerized sequence listing is identical to the paper sequence listing.

Appropriate correction is required.

Claim Rejections/Objections

Claim Objections

Claim 1-3, 7, 9-15 and 23-29 are objected to for reciting or encompassing non-elected inventions (for example, peptides other than SEQ ID NO: 16).

Claim Rejections - 35 USC § 112, first paragraph - enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and

shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7, 9-15 and 23-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for the limitations of the claims wherein a PTH analogue "selectively binds" to the PTH2 receptor, or acts as a selective PTH2 receptor "agonist" or "antagonist."

Claims 1-3, 7, 9-15 and 23-29 are drawn to a PTH analogue that interacts specifically with the PTH2 receptor. Dependent claims recite a peptide of approximately 38 residues with numerous possible substitutions at each residue.

The Specification describes experiments in which several analogues of PTH were synthesized (SEQ ID NO: 16, for example). However, the disclosure does not contain a description of experiments in which binding assays were performed using the PTH2 receptor ligands, or of experiments in which the synthesized analogues were compared to other PTH receptor drugs for their ability to stimulate the receptor or to antagonize known agonists.

A sufficient amount of direction or guidance is lacking in claims 1-3, 7, 9-15 and 23-29. Nowhere in the specification is a method described that identifies a PTH2 receptor agonist or antagonist. Only synthetic methods and tests confirming peptide sequences are described. Therefore, identification of a ligand that "selectively binds" or acts as an "agonist" or "antagonist" and that have the sequences described is not enabled by the instant Disclosure.

Due to the large quantity of experimentation required to --determine how to identify an

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agonist or antagonist of the PTH2 receptor, the lack of direction or guidance in the specification regarding same (e.g., the lack of guidance regarding the functional isolation of PTH2 receptors and subsequent pharmacological assays, and the lack of working examples in which specific PTH2 receptor ligands are used -- undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claim Rejections- 35 USC § 112, first paragraph – Written Description.

Claims 1-3, 7, 9-15 and 23-29 are rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 7, 9-15 and 23-29 are directed to PTH analogues, truncated analogues and compositions of PTH analogues. Dependent claims recite short peptides in which almost every residue may be substituted from a large set of amino acids, or even deleted (Claims 7, 9-15 and 23-29).

The specification teaches several specified polypeptides (for example: SEQ ID NO: 16). However, the specification does not teach functional or structural characteristics of all compounds and all polypeptides encompassed by the claims. The description of one polypeptide PTH analogue (SEQ ID NO: 16) is not adequate written description of an entire genus of functionally equivalent polypeptides and compounds.

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Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

With the exception of the sequence referred to above, the skilled artisan cannot envision the detailed chemical structure of all encompassed PTH analogues, and therefore, would not know how to use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of synthesis or isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a polypeptide comprising the amino acid sequence of SEQ ID NO: 16, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

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References used for an understanding of the art, but not cited in this Office Action:

Marx, U., 1996, Accession No. 1ZWC, chain 32.

Weaver, et al, 1993, Accession No. AAA30749.

Niall, et al, 1992, Accession No. 701028A.

Zhou, et al, 1997, PNAS, 94: 3644-3649.

Usdin, T., 1997, Endocrinology, 138(2): 831-834.

Wright, et al., 1987, PNAS, 84: 26-30.

Conclusion: Claims 1-3, 7, 9-15 and 23-29 are rejected for the reasons recited above.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

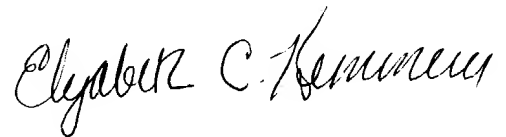
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The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

5/11/04



ELIZABETH KEMMERER
PRIMARY EXAMINER